

EXHIBIT 2
(Rafalski Deposition Transcript)

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL) MDL No. 2804
5 PRESCRIPTION OPIATE)
6 LITIGATION) Case No.
7) 1:17-MD-2804
8)
9 THIS DOCUMENT RELATES TO) Hon. Dan A.
10 ALL CASES) Polster
11)

12
13
14
15
16
17
18
19
20
21
22
23
24
25
Monday, May 13, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E.
RAFALSKI, held at Weitz & Luxenburg PC, 3011
West Grand Avenue, Suite 2150, Detroit,
Michigan, commencing at 9:20 a.m., on the
above date, before Michael E. Miller, Fellow
of the Academy of Professional Reporters,
Registered Diplomate Reporter, Certified
Realtime Reporter and Notary Public.

GOLKOW LITIGATION SERVICES
877.370.3377 ph | fax 917.591.5672
deps@golkow.com

1 A. I guess that's Mr. Prevoznik's
2 issue to comment on.

3 I'm not sure, under my
4 authorization from the DEA, if I even knew I
5 could comment on that.

6 Q. In your report -- and you can
7 turn to the pages if you want. Starting on
8 page 40, you make reference to five different
9 methodologies that address the issue of the
10 number of suspicious orders that were and
11 weren't reported in the Track 1
12 jurisdictions, correct?

13 A. I think I report dosage amounts
14 based on the methodologies.

15 Q. I'm sorry. I'm sorry. I
16 apologize. Dosage amounts.

17 So we're talking about the
18 number of -- however you want to describe it,
19 the number of pills or the number of dosage
20 amounts of pills that are going into these
21 jurisdictions over a period of time; is that
22 right?

23 A. Yes, based on that particular
24 methodology.

25 Q. Okay. Well, you say that

1 particular methodology. You used -- you
2 referenced five methodologies, correct?

3 A. Yes, sir.

4 Q. Okay. Did you figure out those
5 methodologies yourself, or did Mr. McCann do
6 that?

7 A. No, those are mine based on --

8 Q. These five methodologies are
9 yours?

10 A. Yes. Well, they are
11 methodologies that are mirroring suspicious
12 order systems that are utilized by one or
13 more companies in my report.

14 Q. Okay. So did you -- you put
15 these -- did you put these charts together
16 yourself?

17 A. No, I did not.

18 Q. Who put the charts together?

19 A. I -- I'm sorry.

20 Well, this is based on
21 McCann's -- Mr. McCann takes -- took my
22 methodology, and these were the results of
23 his application of my methodology to the
24 ARCOS data.

25 Q. I see.

1 So you -- you came up with
2 these five methodologies?

3 A. Yes, sir.

4 Q. Okay. And tell me -- tell me
5 why you chose these five methodologies. I
6 think you started to do it, but just go ahead
7 and explain it to me.

8 A. Well, because these are
9 methodologies that were used by one or more
10 companies in my report, during the time frame
11 of my report. Each one of these were not
12 invented by me, but they were actually used.

13 Q. Okay. Can you -- let's start
14 with the first one. Methodology A is maximum
15 monthly trailing six-month threshold.

16 Can you explain to me what you
17 were trying to express here?

18 A. Well, this is the Masters case
19 methodology.

20 Q. Okay.

21 A. Or I shouldn't say methodology.
22 This is their suspicious order system. So
23 it's a rolling six-month, and it looks for a
24 current month that exceeds the highest
25 previous amount in the six months.

1 there's any actual written reference to
2 records or the retention of records in that
3 section?

4 A. Well, so in the maintenance of
5 effective controls?

6 Q. Yeah.

7 A. It doesn't specifically say
8 that, if that's what you're...

9 Q. Okay. Okay. Now -- so just --
10 we'll break for lunch, but just so I
11 understand, the methodologies that -- the
12 five methodologies described here were
13 selected -- were identified or selected by
14 you. Is that -- based on what you saw the
15 various companies had done over the years; is
16 that correct?

17 A. Yes, sir.

18 Q. And you provided just those
19 methodologies, the concepts, to Mr. McCann
20 and he plugged in the numbers; is that
21 correct?

22 A. Yes, but just as a
23 clarification, I personally didn't discuss
24 that with Mr. McCann. I discussed it with
25 counsel and then counsel relayed that to

1 BY MR. NICHOLAS:

2 Q. -- at least for the purposes of
3 your numbers?

4 MR. FULLER: Object to form.

5 A. It's not an assumption. It's
6 based on my review of records and depositions
7 and documents that I couldn't find a time
8 period where I believed there was sufficient
9 due diligence -- well, there was actually a
10 complete failure.

11 There was the failure to stop
12 suspicious orders, there was ineffective
13 suspicious order systems, but in regards to
14 what caused these large numbers, it was the
15 failure to have the maintenance of effective
16 controls to prevent diversion, which is the
17 act of the due diligence, the reviewing those
18 orders to approve them as was detailed in the
19 Masters opinion.

20 BY MR. NICHOLAS:

21 Q. Okay. Now, see if we can agree
22 on one thing here, which is this: There
23 could be an order of unusual size or
24 frequency or pattern that is shipped.
25 Whether it should have been or shouldn't have

1 been, we can put aside for another day.
2 Okay? Let's just say that there's an order
3 of unusual size, frequency, pattern, that, in
4 fact, was shipped and it -- you can even
5 say -- and let's say it should have been
6 reported as a suspicious order, but it
7 shipped. All right?

8 Do you agree that even though
9 that order was shipped and even though you
10 say it shouldn't have been shipped, it
11 doesn't necessarily mean that the pills that
12 underlie that order are going to be diverted.
13 You don't know.

14 MR. FULLER: Object to form.

15 BY MR. NICHOLAS:

16 Q. Correct?

17 A. So I'll answer that question by
18 saying that if it's identified as suspicious
19 order by unusual size or unusual frequency or
20 deviating form -- you know, substantial
21 deviation from a pattern, so to me that puts
22 it as a probable, greater than 51% that it's
23 going to be diverted because it's been
24 identified.

25 So I can't draw the conclusion

1 that I don't know that it's going to be
2 diverted. I probably can't draw a definitive
3 statement that it is, but I'm going to say
4 that it's more probable because the system
5 identified it.

6 Q. So you got it at 51% above,
7 it's going to be diverted; is that what
8 you're telling me?

9 A. Well, that's the definition of
10 probable. If it's an effective suspicious
11 order system, I believe the percents would
12 rise much higher than that, but I guess that
13 depends on the effectiveness of the
14 suspicious order system.

15 Q. Where are you getting that
16 percent from? Where are you getting that
17 from, just your own --

18 A. What?

19 Q. The 51, the probable, where are
20 you getting that it's probable?

21 A. That's my belief of what
22 probable means.

23 Q. Okay. Other than your belief,
24 is it written down anywhere? Is there any
25 research on that? Is there any data on that?

1 Is this just -- just your belief?

2 A. Not that I can cite.

3 Q. Okay.

4 MR. FULLER: Vegas odds.

5 MR. NICHOLAS: Okay.

6 BY MR. NICHOLAS:

7 Q. Did you look at any individual
8 orders from any pharmacies in the Cuyahoga or
9 Summit Counties?

10 A. I looked at some DEA 222 forms,
11 but I believe my recollection, it was out of
12 maybe the Boston area, so I would say no.

13 Q. Okay.

14 A. No original records. I
15 reviewed no original records.

16 Q. You reviewed data that was in
17 the aggregate, right, totals? Correct?

18 A. No. I reviewed -- so just so
19 we're clear on, you know, what we're talking
20 about, so there's no confusion.

21 Q. Uh-huh.

22 A. So to me, in the DEA world, an
23 original record is the actual DEA order form,
24 the invoice or a CSOS electronic order form.
25 So that's what I would consider an original

1 defendant a little bit.

2 A. Oh, okay.

3 Q. So if there's 13 defendants, is
4 it roughly spread evenly, divided by 13, you
5 get a rough approximation?

6 A. Well, I think I spent a little
7 more time on the distributors until I did
8 the -- instead of the manufacturers. I would
9 say I probably spent more time in totality
10 and individually in -- as far as just at the
11 distributors.

12 I would probably say pretty
13 equal except with Henry Schein, because
14 that's a smaller distributor and there was
15 less documents and less information to
16 review.

17 Q. So for each of the larger
18 distributors, we're talking something in the
19 range of 50 or 60 hours each; is that fair?

20 A. I guess that could be a
21 possible --

22 MR. FULLER: Object to form.

23 A. I guess it could be a possible
24 approximation.

25 BY MR. PYSER:

1 Q. Okay. But you're the -- you're
2 the guy, you're the expert on what's an
3 effective SOM system and what's not an
4 effective SOM system for the plaintiffs,
5 right?

6 A. I am.

7 Q. And there's not another
8 individual who's been designated as an expert
9 by the plaintiffs to help you in analyzing
10 whether or not a SOM system is compliant or
11 noncompliant?

12 A. That is a correct statement,
13 yes, sir.

14 Q. Okay. And sitting here today,
15 you don't know the number of suspicious
16 orders that Henry Schein has distributed into
17 Summit County?

18 A. If you're asking do I have a
19 specific number of orders, I do not.

20 Q. Okay. In fact, you don't know
21 if any suspicious orders have been
22 distributed by Henry Schein into Summit
23 County, do you?

24 A. I don't state that in my
25 report, no, sir.

1 Q. Okay. And similarly, you don't
2 know what, if any, orders that Henry Schein
3 distributed into Summit County were diverted?

4 (Document review.)

5 A. I do not have knowledge of any
6 drugs that were diverted.

7 BY MR. JONES:

8 Q. As part of your work in this
9 case, you reviewed Henry Schein's standard
10 operating procedures?

11 A. Yes, sir.

12 Q. Or SOPs?

13 A. Yes, sir.

14 Q. You also reviewed Henry Schein
15 witness deposition testimony?

16 A. I'm just checking. I don't
17 have a recollection of that.

18 (Document review.)

19 A. Yes, sir, I believe I did.

20 BY MR. JONES:

21 Q. Do you recall whose?

22 A. Abreu.

23 Q. Is that a man or a woman, do
24 you know?

25 A. I don't recall. I remember the

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL) MDL No. 2804
5 PRESCRIPTION OPIATE)
6 LITIGATION) Case No.
7) 1:17-MD-2804
8)
9 THIS DOCUMENT RELATES TO) Hon. Dan A.
10 ALL CASES) Polster
11)

12
13
14
15
16
17
18
19
20
21
22
23
24
25
Tuesday, May 14, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E.
RAFALSKI, VOLUME 2, held at Weitz &
Luxenburg PC, 3011 West Grand Avenue, Suite
2150, Detroit, Michigan, commencing at
8:25 a.m., on the above date, before
Michael E. Miller, Fellow of the Academy of
Professional Reporters, Registered Diplomate
Reporter, Certified Realtime Reporter and
Notary Public.

GOLKOW LITIGATION SERVICES
877.370.3377 ph | fax 917.591.5672
deps@golkow.com

1 yesterday that you did not review any of the
2 flagged orders from Dr. McCann's analysis; is
3 that correct?

4 A. I think my testimony in that
5 area was any specific orders. That would be
6 correct of what my testimony was, yes.

7 Q. You did not do any analysis to
8 see whether any specific suspicious order
9 caused the diversion of any specific pills
10 for nonmedical use, correct?

11 A. In regards to Dr. McCann's --

12 Q. Correct.

13 A. That would be a correct
14 statement. I didn't do a specific order of a
15 specific drug, if I understand your question
16 properly.

17 Q. Well, you asked for a
18 clarification of whether I was speaking about
19 Dr. McCann's analysis.

20 You didn't do any analysis to
21 see whether any specific suspicious order
22 caused the diversion of any specific pills,
23 correct?

24 MR. FULLER: Object to form.

25 A. I think that's an accurate

1 statement.

2 BY MS. SWIFT:

3 Q. You testified yesterday that
4 you endorsed Flagging Method A, which you can
5 see at the top of page 41 of your report.
6 Because it -- is that correct?

7 A. I think that's an accurate
8 statement. It was -- I endorsed it because
9 it was utilized by the Masters
10 Pharmaceutical.

11 Q. Is that the only reason you
12 endorsed Flagging Method A?

13 A. No, that wouldn't be the only
14 reason, no, ma'am.

15 Q. Did any of the plaintiffs'
16 lawyers instruct or suggest to you that you
17 use Flagging Method A?

18 A. No.

19 Q. What other reasons did you
20 endorse Flagging Method A?

21 A. One, it was part of one of the
22 investigations I conducted, so I was familiar
23 with it. I believe it was discussed at an
24 administrative hearing with the DEA,
25 subsequently reviewed by the D.C. Court, and

1 Q. You don't have an opinion about
2 whether any particular order -- you didn't
3 look at any particular order to see whether
4 it was diverted to an illicit channel?

5 A. I did not --

6 Q. Okay.

7 A. -- analyze all the orders and
8 try to find one or locate one that was
9 diverted.

10 Q. You didn't analyze any of the
11 orders, correct, sir?

12 A. That's correct.

13 Q. You have no opinion about
14 whether any particular order that was flagged
15 as suspicious led to someone's addiction,
16 overdose or death, correct, sir?

17 A. As of today, I have no opinion
18 on that matter.

19 Q. Do you plan on coming up with
20 that opinion at some point after today?

21 A. I can't rule that out if I'm
22 asked to look at that or I'm provided some
23 information I could review that would -- that
24 would indicate that. So I can't rule out
25 that that would occur.

1 wouldn't have mattered in your hypothetical.

2 Would you agree with me on
3 that?

4 It's a risk of -- maybe we can
5 grant you that, but if the risk never came
6 home to roost, then it doesn't matter, but
7 you don't know that.

8 A. Well, that's it. The concept
9 of why we're not agreeing on this is the
10 suspicious order system and the effectiveness
11 of it and the due diligence is all based on
12 the risk of diversion. It doesn't mean that
13 diversion is going to occur. Just based on
14 the serious risk, and that's what makes it a
15 maintenance of effective controls requirement
16 by the law.

17 Q. All right. Take a look at
18 page 108. So this -- I want to direct your
19 attention to the top of page 108. You say:
20 Mortelliti testified that while he was
21 reviewing the IRR, every HCP order that
22 appeared on the IRR was referred out for
23 additional investigation which he believed
24 was necessary.

25 With me so far?

1 MR. O'CONNOR: Objection, form.

2 MR. FULLER: I'm sorry, go
3 ahead.

4 A. Any relevant transactions.

5 MR. FULLER: I don't have
6 anything further.

7 THE VIDEOGRAPHER: Going off
8 the record, 5:04 p.m.

9 (Recess taken, 5:04 p.m. to
10 5:14 p.m.)

11 THE VIDEOGRAPHER: We're back
12 on the record at 5:14 p.m.

13 EXAMINATION

14 BY MR. MATTHEWS:

15 Q. Good afternoon, Mr. Rafalski.
16 I already introduced myself to you but just
17 for the record, I'm James Matthews. I
18 represent Anda Inc.

19 A. Good afternoon.

20 Q. How are you.

21 I want to take you back to the
22 beginning of the day. There were some
23 questions asked of you by Ms. Swift who
24 represented Walgreens.

25 Do you remember that very

1 beginning of the day, right in the morning?

2 A. I recall I was interviewed or
3 deposed about Walgreens. I don't
4 specifically -- the questions, I don't
5 recall.

6 Q. Okay. You issued 183 --
7 180-some-odd-page report, right?

8 A. Yes, sir.

9 Q. And in that, you set forth your
10 opinions, and you told Ms. Swift that all of
11 your opinions are in that report, right?

12 A. Of the companies that I
13 evaluated, the opinion -- of -- yes.

14 Q. Yes.

15 And the bases for those
16 opinions, except insofar as they're based on
17 your own personal experience and knowledge,
18 are in the footnotes to that report, right?

19 MR. FULLER: I'm going to
20 object, and if I can have a running
21 objection that this is outside my
22 cross.

23 MR. MATTHEWS: That's fine, you
24 can have your objection, thank you.

25 MR. FULLER: Thank you.

1 A. I think it's an accurate
2 statement. It was based on the review of the
3 records that I cited.

4 BY MR. MATTHEWS:

5 Q. Okay. There's not a single
6 document created by Anda Inc. cited in any of
7 the footnotes in your report, right?

8 A. That's correct.

9 Q. And that means that there's --
10 and there's no depositions of any Anda Inc.
11 employees cited in any of the footnotes of
12 your report, right?

13 A. There is not.

14 Q. In fact, you haven't done
15 anything to look at Anda's suspicious order
16 monitoring program, right?

17 A. I have not.

18 Q. And since there's no
19 information that would be the basis for any
20 opinions as to Anda's suspicious order
21 monitoring system in your report, it's safe
22 to say that there are no opinions about
23 Anda Inc. in your report, right?

24 A. There's no opinions of Anda in
25 the current report, right here, no, sir.

1 Q. And so I'd like you, if you
2 could, to just open your report to page 7.
3 You know that Anda, Inc. is one of the
4 defendants in this action, right?

5 A. I believe so, yes, sir.

6 Q. Okay. Looking at page 7 of
7 your report, in the second full paragraph,
8 you wrote: I am of the opinion to a
9 reasonable degree of professional certainty
10 that there was a systematic, prolonged
11 failure over many years by the defendant
12 manufacturers and distributors to maintain
13 effective controls against diversion of
14 legitimate opioid prescriptions into the
15 illicit market.

16 Did I read that correctly?

17 A. You did.

18 Q. So Anda is a defendant, right?

19 A. Yes, sir.

20 Q. And that opinion as described
21 on page 7 does not apply to Anda, right?

22 A. As I sit here today, no, I have
23 not reviewed any records related to Anda.

24 Q. Okay. I want to ask one more
25 question following up on your testimony.